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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,444	02/24/2004	Anthony Pantages	16497.4.1	4902

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WORKMAN NYDEGGER
1000 EAGLE GATE TOWER,
60 EAST SOUTH TEMPLE
SALT LAKE CITY, UT 84111

EXAMINER

YABUT, DIANE D

ART UNIT	PAPER NUMBER
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3734

MAIL DATE	DELIVERY MODE
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08/31/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/786,444	Applicant(s) PANTAGES ET AL.	
	Examiner Diane Yabut	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-10 and 12-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-10 and 12-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 17 August 2007 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. On lines 11-12 of Claim 1 it reads "expanding said one or more positioning elements from a non-stressed state to a stressed state," and it is not supported or mentioned in the specification, or is unclear as to how the positioning elements expand from a non-stressed state to a stressed state.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 2, 3, 5, 7-10, and 12-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al., or **Green** (U.S. Patent No. **5,674,231**) in view of Martinez et al., or **Martinez** (U.S. Patent No. **5,593,412**).

Claims 1, 17, 19, 20, and 22: Green discloses a method for delivering a closure element **102** in a blood vessel **104**, the closure element being carried by a carrier assembly **42** slidable on an outer surface of an elongate member **30**, the elongate member comprising and at least partially overlying the carrier assembly, the elongate member being provided with a locator member **60** slidably associated therewith, the locator member having one or more expandable positioning elements **62**, **64** on its distal portion, the method comprising inserting the distal end of the elongate member into an opening through tissue, advancing the locator member distally from the distal end of the elongate member, expanding the one or more positioning elements from a non-stressed state to a stressed state, withdrawing the locator member until the positioning elements contact tissue, advancing the carrier assembly towards the distal end of the elongate member, and deploying the closure element from the carrier assembly within the opening to substantially seal the opening (Figures 1-4, 7, 10-11 and col. 5, lines 45-67, col. 6, lines 1-8, col. 7, lines 18-67, col. 8, lines 1-52). Green

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discloses the claimed invention except for a skin, or sleeve member, overlying at least a portion of the outer surface between the carrier assembly and a distal end of the elongate member and a the carrier assembly causing the skin to separate from the outer surface of the elongate member as the carrier assembly is advanced towards the distal end.

Martinez teaches a skin, or sleeve, **18** overlying at least a portion of the outer surface between the carrier assembly and a distal end of the elongate member and the carrier assembly causing the skin to separate from the outer surface of the elongate member as the carrier assembly is advanced towards the distal end (Figures 1-5 and col. 4, lines 53-67 and col. 5, lines 1-2). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a skin, as taught by Martinez, to Green since it was known in the art that skins or sheaths are commonly used in deployment devices to conveniently protect delivery devices and are often subsequently opened or removed in order to unveil the delivery device without additional manipulation by a secondary instrument or mechanism.

Claim 2: Green discloses removing the elongate member from the opening (col. 8, lines 44-52).

Claims 3 and 5: Green discloses the claimed invention except for the skin comprising a weakened region extending towards the distal end of the elongate member, the weakened region tearing as the carrier assembly is advanced towards the distal end of the elongate member, and the skin expanding to a cross-section that is larger than a

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cross-section of the elongate member as the carrier assembly is advanced towards the distal end.

Martinez teaches a skin comprising a weakened region extending towards the distal end of the elongate member, the weakened region tearing as the carrier assembly is advanced towards the distal end of the elongate member, and the skin expanding to a cross-section that is larger than a cross-section of the elongate member as the carrier assembly is advanced towards the distal end (Figures 1-5 and col. 4, lines 53-67 and col. 5, lines 1-2). It would have been obvious to one of ordinary skill in the art to provide a skin with a weakened region, as taught by Martinez, to Green since it was known in the art that skins or sheaths are commonly used in deployment devices to protect delivery devices with weakened regions to serve as a simple opening mechanism that does not require a second instrument or mechanism.

Claim 7: Green discloses the claimed invention except for the skin comprising an outer surface that is substantially slippery for facilitating advancement of the elongate member into the opening through tissue.

Martinez teaches the skin comprising an outer surface that is substantially slippery for facilitating advancement of the elongate member into the opening through tissue and that it allows for retraction of the sheath and allows for expansion for the element onto which it is disposed (col. 3, lines 30-42 and col. 4, lines 53-67 and col. 5, lines 1-2). It would have been obvious to one of ordinary skill to provide a skin with a slippery outer surface, as taught by Martinez, to Green since it was known in the art that a lubricated, slippery surfaces allow for facilitated translational movement and also in

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order to allow for expansion of the elongate member or the element onto which it is disposed.

Claim 8: Green and Martinez disclose the claimed invention except for the opening through tissue extending through one or more layers of fascia, and wherein the skin facilitates advancement of the carrier assembly through the one or more layers of fascia. It would have been obvious to one of ordinary skill in the art for the skin to facilitate advancement of the carrier assembly through one or more layers of fascia, or connective tissues of the blood vessel, in Green and Martinez, since it was known in the art that sheaths and skins protect as well as facilitate advancement of deployment devices through layers of tissue in the surgical site.

Claim 9: Green discloses the opening through tissue communicating with a blood vessel, and wherein the deploying step comprises substantially sealing the opening from blood flow therethrough with the closure element. See explanation for Claims 1, 17, 19, 20, and 22 above.

Claim 10: Green discloses coupling the carrier assembly to a proximal end of the elongate member. See explanation for Claims 1, 17, 19, 20, and 22 above.

Claims 12-13: Green discloses the claimed invention except for the skin comprising a plurality of longitudinal slots, the slots opening as the carrier assembly is advanced, thereby expanding the skin, and the slots being staggered relative to one another such that the skin assumes a zigzag mesh configuration as it expands.

Martinez teaches a skin comprising a plurality of longitudinal slots, the slots opening as the carrier assembly is advanced, thereby expanding the skin, and the slots

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being staggered relative to one another such that the skin assumes a zigzag mesh configuration as it expands (Figures 1-5 and col. 4, lines 53-67 and col. 5, lines 1-2). It would have been obvious to one of ordinary skill in the art to provide a skin having a plurality of slots assuming a zigzag mesh configuration, as taught by Martinez, to Green since it was known in the art that this configuration allows for more flexibility and lateral, axial, and longitudinal expansion.

Claim 14: Green discloses contracting said positioning elements and withdrawing said locator member. See explanation for Claims 1, 17, 19, 20, and 22 above.

Claim 15: Green discloses the distal end of the elongate member being inserted into the lumen of a blood vessel and wherein the positioning elements of the locator member are expanded within the lumen of a blood vessel. See explanation for Claims 1, 17, 19, 20, and 22 above.

Claim 16: Green discloses the step of withdrawing the locator member causes the positioning elements to come into contact with the wall of the blood vessel. See explanation for Claims 1, 17, 19, 20, and 22 above.

Claims 18 and 21: Green and Martinez disclose the claimed invention except for the blood vessel being the femoral artery. It would have been obvious to one of ordinary skill to provide the blood vessel as being a femoral artery in Green and Martinez, since it was known in the art that the femoral artery is a blood vessel and that the vascular hole closure device and method may be applied to any blood vessel.

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3. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Green** (U.S. Patent No. **5,674,231**) and **Martinez** (U.S. Patent No. **5,593,412**), as applied to Claim 1 above, and further in view of Kanner et al., or **Kanner** (U.S. Patent No. **5,868,755**).

Claim 6: Green and Martinez disclose the claimed invention except for the skin being bonded to the outer surface of the elongate member by an adhesive and wherein the adhesive has sufficient adhesive strength such that the skin is peeled away from the outer surface as the carrier assembly is advanced towards the distal end.

Kanner teaches a skin **1** being bonded to the outer surface of the elongate member by an adhesive and wherein the adhesive has sufficient adhesive strength such that the skin is peeled away from the outer surface as the carrier assembly is advanced towards the distal end (col. 4, lines 1-16). It would have been obvious to one of ordinary skill in the art to provide a skin bonded to the outer surface to the elongate member, as taught by Kanner, to Green and Martinez, since it was known in the art to provide adhesives that provide temporary security and to avoid undesired movement of the sheath.

Response to Arguments

4. Applicant's arguments filed 17 August 2007 have been fully considered but they are not persuasive.

5. The applicant argues that Green et al. discloses the positioning device going from a "collapsed (stressed) position" position to a "deployed (unstressed)" position,

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which contrasts to the recitation "expanding said one or more positioning elements from a non-stressed state to a stressed state" in lines 11-12 of Claim 1. The examiner disagrees. Green et al. reads on the limitations of Claim 1, as the present invention requires that positioning elements go from a non-stressed state, or a "substantially axial collapsed configuration," to a "substantially transverse expanded configuration," as seen on page 22, lines 16-21 of the specification, which Green et al. also teaches, as maintained above (also see col. 6, lines 57-60). Given that there is no support as to what "stressed" and "unstressed" require in the present invention, the examiner may interpret a "non-stressed state" as being a state in which the positioning element is not in contact with the tissue and conversely a "stressed state" being a state in which the positioning element is in contact with tissue. Therefore, the device of Green et al. reads on the limitations of Claim 1.

6. The applicant generally argues that Martinez et al. and Green et al. have conflicting functional operations, considering the device of Green et al. passes from outside the body to just inside the blood vessel to close a hole formed therein, and the device of Martinez et al. is directed to opening a vessel by implanting a stent within a lesion within a vessel, and therefore one skilled in the art would not look to Martinez et al. to modify Green et al. The applicant also argues that there would be no need to modify Green et al. with the sheath of Martinez et al. since the device of Green et al. is deployed through a conventional cannula. In response to applicant's argument that Martinez is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the

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particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. The teaching cited above by Martinez et al. is one that centers on the benefit of minimizing trauma to the blood vessel during deployment of a device by using a skin or sleeve that may be conveniently opened or removed in order to unveil a delivery device, and is made of a material that not only is less irritating to tissue, but also facilitates retraction as it is capable of expansion (see col. 3, lines 19-42).

7. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. In this case, it would have been obvious to one of ordinary skill in the art to be more efficient in deploying a clip by utilizing a skin that could be easily removed.

8. Lastly, applicant argues that Martinez et al. teaches proximal movement of the skin or sleeve rather than moving a carrier assembly towards a distal end of the elongate member to cause the sleeve member to be disrupted or expanded. However, the carrier assembly 12, 20 of Martinez is one that moves distally (see movement from Figure 3 to Figure 5), which results in an easy withdrawal of the skin 18. When combined with the device of Green et al., it would also be evident that the skin would be

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easily retracted after expansion as the carrier assembly is moved to the distal end of the elongate member. The examiner asserts that the test for obviousness is what the combined teachings of the references would have suggested to those of ordinary skill in the art, and what Martinez et al. suggests is that commonly used skins or sleeves in deployment devices are conveniently opened or removed as they are made of a material that not only is less irritating to tissue, but also facilitates retraction as it is capable of expansion.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY

A handwritten signature in black ink, appearing to read "M J Hayes", with a stylized flourish at the end.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER